

Request for Section 18 emergency use of Sulfoxaflor (Transform® WG Insecticide) to control sugarcane aphid (*Melanaphis* sp.) in sorghum fields (grain, forage) in the state of Kentucky.

Type of Exemption Kentucky Section 18; Specific Exemption Request; July 28, 2017.

This is an application for a specific exemption to authorize the use of Sulfoxaflor (Transform® WG Insecticide EPA Reg. No. 62719-625) to control the newly introduced sugarcane aphid (SCA), *Melanaphis* sp. in sorghum. The following information is submitted in the format indicated in the proposed rules for Chapter 1, Title 40 CFR, Part 166.

SECTION 166.20(a)(1): IDENTITY OF CONTACT PERSONS

- i. The following are the contact persons responsible for the administration of the emergency exemption:

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Pesticide Aspects

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SECTION 166.20(a)(2): DESCRIPTION OF THE PESTICIDE REQUESTED

i. **Common Chemical Name (Active Ingredient):** Sulfoxaflor

Brand/Trade Name and EPA Reg. No.: Transform® WG Insecticide,
EPA Reg. No. 62719-625

Formulation: Active Ingredient 50%

SECTION 166.20(a)(3): DESCRIPTION OF THE PROPOSED USE

i. **Sites to be treated:**

Sorghum fields (grain, forage) with the newly introduced sugarcane aphid (SCA), *Melanaphis sp.* statewide.

ii. **Method of Application:**

The proposed method of application will be a foliar application when sugarcane aphid populations reach the recommended economic threshold values.

iii. **Rate of Application:**

0.75 – 1.5 oz of Transform® WG/acre (0.023 – 0.047 lb ai/acre).

iv. **Maximum Number of Applications:**

Three applications per year (season maximum of 3 oz/acre or 0.094 lb ai/acre)

v. **Total Acreage to be Treated:**

According to the National Agricultural Statistics Service (NASS), 13,000 acres of sorghum was planted in Kentucky in 2008 (the last year statistics were available). However, a conservatively estimate is that 20,000 acres of sorghum will be planted in 2017.

vi. **Total Amount of Pesticide to be Used:**

Based on the estimated amount of acreage in Kentucky, if all 13,000 acres of sorghum were treated with the maximum seasonal use rate (3.0 oz/acre or 0.094 lb ai/acre), then 2,437 pounds of Transform® WG would be used in 2017.

vii. Restrictions and Requirements:

Refer to the Transform® WG container label for first aid, precautionary statements, directions for use and conditions of sale and warranty information. It is a violation of federal law to use this product in a manner that is inconsistent with all applicable label directions, restrictions and precautions found in the container label and this supplemental label. Both the container label and this supplemental Section 18 quarantine exemption label must be in the possession of the user at the time of application.

- Applicable restrictions and requirements concerning the proposed use and the qualifications of applicators using Transform® WG are as follows:
 - Pre-harvest Interval: Do not apply within 7 days of harvest for grain or 14 days of harvest for forage or stover.
 - Minimum Treatment Interval: Do not make applications less than 14 days apart.
 - Do not make more than three applications per acre per year.
 - Do not apply more than a total of 3.0 oz of Transform WG (0.094 lb ai of sulfoxaflor) per acre per year.

viii. Duration of the Proposed Use:

May through November.

ix. Earliest Possible Harvest Date:

Late August in Kentucky.

SECTION 166.20(a)(4): ALTERNATIVE METHODS OF CONTROL

As documented in numerous tests, other insecticides currently labeled in sorghum provide no or inconsistent control of sugarcane aphid. Specifically, Lorsban (chlorpyrifos) and Dimethoate have provided less than satisfactory control in many tests during 2014. Furthermore, pre-harvest application restrictions of Lorsban and Dimethoate limit their use later in the season. Sivanto appears to be a viable and now labeled option for control. However, the efficacy of 2ee rates (4-7 oz) have not been well evaluated, and higher rates are economically unviable. It appears, based on 2014 data in collected in Mississippi and Arkansas, that insecticide seed treatments of Poncho (clothianidin) or Cruiser (thiamethoxam) provide control of sugarcane aphids for 30-40 days. Hopefully, utilizing seed treatments, Transform WG, and Sivanto can help to manage potential insecticide resistance. Perhaps the best way to manage insecticide resistance is to only treat as needed. Thus, UK Extension is encouraging growers to follow sound IPM principles such as planting early and avoiding unnecessary insecticide application that may flare populations of SCA

SECTION 166.20(a)(5): EFFICACY OF USE PROPOSED UNDER SECTION 18

Other Section 18 applicants have provided substantial data showing the relative efficacy of Transform WG on sugarcane aphid in sorghum. The Louisiana Section 18 request included trials by Dr. David Kerns to measure the efficacy of products to control sugarcane aphid infestations in sorghum. These field trials indicated that sulfoxaflor, Transform® WG, at 1 oz/acre provided greater than 90% control of sugarcane aphids, whereas other products provided no greater than 50% control (see attachments). More recent insecticide evaluations in Mississippi and Arkansas have shown that currently labeled sorghum insecticides, with the possible exception of Sivanto, did not provide dependable residual control. Transform was the most tested and best choice for control of sugarcane aphids in many tests (see below).

University of Arkansas CES (Gus Lorenz) Sugarcane Aphid Trial #1

				3 DAA	6 DAA
Description				Aphids/25 flag>	Aphids/25 flag>
Rating Date				8/1/2014	8/4/2014
Rating Type				scale 1-3	scale 1-3
Rating Unit				avg	avg
Number of Subsamples				1	1
ARM Action Codes				AL	
Trt No.	Treatment Name	Rate	Unit		
				1	2
1	UTC			1.86 a	2.65 a
2	Sivanto	10	oz/a	1.07 cde	1.05 cd
3	CMT 4586	8	oz/a	1.04 de	1.00 cd
	Dyne-Amic	0.25	% v/v		
	UAN	2.5	% v/v		
4	Calypso	2	oz/a	1.58 ab	2.00 b
5	Transform	0.75	oz/a	0.92 e	1.18 cd
6	Transform	1.0	oz/a	1.01 de	0.93 d
7	Transform	1.5	oz/a	0.95 e	0.68 d
8	Carbine	2.5	oz/a	1.44 a-d	2.08 b
9	Intruder	3	oz/a	1.55 abc	1.55 bc
10	Lannate	1.5	pt/a	0.96 e	1.88 b
11	Centric	2.5	oz/a	1.30 b-e	1.18 cd
LSD (P=.10)				0.084t	0.542
Treatment F				2.952	7.273
Treatment Prob(F)				0.0105	0.0001

Mississippi State University (Angus Catchot) Sugarcane Aphid Trial (rating 7/21/14, 5 DAA)

Insecticide	Rate/acre	Rating (0-3 scale)
Transform	1 oz	0.3 c
Carbine	2 oz	1.1 b
Lorsban Advanced	16 Oz	1.5 ab
Lorsban Advanced	32 oz	1.7 ab
Untreated	---	2.1 a

P < 0.05

University of Arkansas CES (Gus Lorenz)
Sugarcane Aphid Trial #2

				3 DAA	6 DAA
Description				Aphids/25 flag>	Aphids/25 flag>
Rating Date				8/1/2014	8/4/2014
Rating Type				scale 1-3	scale 1-3
Rating Unit				avg	avg
Number of Subsamples				1	1
Trt No.	Treatment Name	Rate	Rate Unit	1	2
1	UTC			1.65 a	2.63 a
2	Transform	0.75	oz/a	1.03 bc	0.75 de
	COC	1	% v/v		
3	Transform	1.5	oz/a	0.78 cd	0.65 e
	COC	1	% v/v		
4	Lorsban Advanced	0.75	qt/a	0.55 d	0.93 cde
	COC	1	% v/v		
5	Cobalt Advanced	24	oz/a	1.40 ab	2.28 ab
	COC	1	% v/v		
6	Dimethoate	16	oz/a	1.33 ab	2.00 b
	COC	1	% v/v		
7	Endigo ZCX	5	oz/a	1.13 bc	1.15 cd
	COC	1	% v/v		
8	Admire Pro	3	oz/a	1.30 ab	1.20 c
	COC	1	% v/v		
LSD (P=.10)				0.363	0.399
Treatment Prob(F)				0.0009	0.0001

The University of Tennessee (Scott Stewart)
Sugarcane Aphid Trial (rating 9/2/14, 6 DAA), Hardeman County

Rating Unit				% Aphid Control*	
Rating Date				9/2/2014	
Sample Size, Unit				25 Leaves	
Treatment	Formulation	Rate			
1 Lorsban	4 LB/GAL	24 fl oz/a		60.3	bcd
2 Admire Pro	4.6 LB/GAL	1.7 fl oz/a		79.6	cde
3 Transform	50 %	1.0 oz wt/a		89.3	e
4 Transform	50 %	1.5 oz wt/a		91.4	e
5 Centric	40 %	2 oz wt/a		64.6	b-e
6 Carbine	50 %	2 oz wt/a		55.0	bc
7 Dimethoate	4 LB/GAL	16 fl oz/a		41.1	b
8 Sivanto	200 G/L	5 fl oz/a		88.2	de
9 Sivanto	200 G/L	7.5 fl oz/a		87.1	de
10 Experimental	100 G/L	10 fl oz/a		81.5	cde
11 Untreated				0.0	a

*Untreated plots averaged about 30 aphids/leaf.

Means followed by same letter do not significantly differ ($P=.05$, LSD).

SECTION 166.20(a)(6): EXPECTED RESIDUES FOR FOOD USES

Acute Assessment

Food consumption information from the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and maximum residues from field trials rather than tolerance-level residue estimates were used. It was assumed that 100% of crops covered by the registration request are treated and maximum residue levels from field trials were used.

Drinking water. Two scenarios were modeled, use of sulfoxaflor on non-aquatic row and orchard crops and use of sulfoxaflor on watercress. For the non-aquatic crop scenario, based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of sulfoxaflor for acute exposures are 26.4 ppb for surface water and 69.2 ppb for ground water. For chronic exposures, EDWCs are 13.5 ppb for surface water and 69.2 ppb for ground water. For chronic exposures for cancer assessments, EDWCs are 9.3 ppb for surface water and 69.2 ppb for ground water. For the watercress scenario, the EDWCs for surface water are 91.3 ppb after one application, 182.5 ppb after two applications and 273.8 ppb after three applications.

Dietary risk estimates using both sets of EDWCs are below levels of concern. The non-aquatic-crop EDWCs are more representative of the expected exposure profile for the majority of the population. Also, water concentration values are adjusted to take into account the source of the water; the relative amounts of parent sulfoxaflor, X11719474, and X11519540; and the relative liver toxicity of the metabolites as compared to the parent compound.

For acute dietary risk assessment of the general population, the groundwater EDWC is greater than the surface water EDWC and was used in the assessment. The residue profile in groundwater is 60.9 ppb X11719474 and 8.3 ppb X11519540 (totaling 69.2 ppb). Parent sulfoxaflor does not occur in groundwater. The regulatory toxicological endpoint is based on neurotoxicity.

For acute dietary risk assessment of females 13-49, the regulatory endpoint is attributable only to the parent compound; therefore, the surface water EDWC of 9.4 ppb was used for this assessment.

A tolerance of 0.3 ppm for sulfoxaflor on grain sorghum has been established. There is no expectation of residues of sulfoxaflor and its metabolites in animal commodities as a result of the proposed use on sorghum. Thus, animal feeding studies are not needed, and tolerances need not be established for meat, milk, poultry, and eggs.

Drinking water exposures are the driver in the dietary assessment accounting for 100% of the exposures. Exposures through food (sorghum grain and syrup) are zero.

The acute dietary exposure from food and water to sulfoxaflor is 16% of the aPAD for children 1-2 years old and females 13-49 years old, the population groups receiving the greatest exposure.

Chronic Assessment

The same refinements as those used for the acute exposure assessment were used, with two exceptions: (1) average residue levels from crop field trials were used rather than maximum values and (2) average residues from feeding studies, rather than maximum values, were used to derive residue estimates for livestock commodities. It was assumed that 100% of crops are treated and average residue levels from field trials were used.

For chronic dietary risk assessment, the toxicological endpoint is liver effects, for which it is possible to account for the relative toxicities of X11719474 and X11519540 as compared to sulfoxaflor. The groundwater EDWC is greater than the surface water EDWC. The residue profile in groundwater is 60.9 ppb X11719474 and 8.3 ppb X11519540. Adjusting for the relative toxicity results in 18.3 ppb equivalents of X11719474 and 83 ppb X11519540 (totaling 101.3 ppb). The adjusted groundwater EDWC is greater than the surface water EDWC (9.3 ppb) and was used to assess the chronic dietary exposure scenario.

The maximum dietary residue intake via consumption of sorghum commodities would be only a small portion of the RfD (<0.001%) and therefore, should not cause any additional risk to humans via chronic dietary exposure. Consumption of sorghum by sensitive sub-populations such as children and non-nursing infants is essentially zero. Thus, the risk of these subpopulations to chronic dietary exposure to sulfoxaflor used on grain sorghum would be insignificant.

The major contributor to the risk was water (100%). There was no contribution from grain sorghum to the dietary exposure. All other populations under the chronic assessment show risk estimates that are below levels of concern.

Chronic exposure to sulfoxaflor from food and water is 18% of the cPAD for infants, the population group receiving the greatest exposure. There are no residential uses for sulfoxaflor.

Short-term risk. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed, no further assessment of short-term risk is necessary, the chronic dietary risk assessment for evaluating short-term risk for sulfoxaflor is sufficient.

Intermediate-term risk. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no residential exposure and chronic dietary exposure has already been assessed, no further assessment of intermediate-term risk is necessary.

Cumulative effects. Sulfoxaflor does not share a common mechanism of toxicity with any other substances, and does not produce a toxic metabolite produced by other substances. Thus, sulfoxaflor does not have a common mechanism of toxicity with other substances.

Cancer. A nonlinear RfD approach is appropriate for assessing cancer risk to sulfoxaflor. This approach will account for all chronic toxicity, including carcinogenicity that could result from

exposure to sulfoxaflor. Chronic dietary risk estimates are below levels of concern; therefore, cancer risk is also below levels of concern.

There is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sulfoxaflor as used in this emergency exemption request.

The content in the above Section 166.20(a)(6): “Expected Residues For Food Uses” was prepared by Michael Hare, Ph.D., Texas Department of Agriculture.

SECTION 166.20(a)(7): DISCUSSION OF RISK INFORMATION

Human Health Effects – Michael Hare, Ph.D.

Ecological Effects – David Villarreal, Ph.D.

Environmental Fate – David Villarreal, Ph.D.

Human Health

Toxicological Profile

Sulfoxaflor is a member of a new class of insecticides, the sulfoximines. It is an activator of the nicotinic acetylcholine receptor (nAChR) in insects and, to a lesser degree, mammals. The nervous system and liver are the target organs, resulting in developmental toxicity and hepatotoxicity.

Developmental toxicity was observed in rats only. Sulfoxaflor produced skeletal abnormalities likely resulting from skeletal muscle contraction due to activation of the skeletal muscle nAChR in utero. Contraction of the diaphragm, also related to skeletal muscle nAChR activation, prevented normal breathing in neonates and increased mortality. The skeletal abnormalities occurred at high doses while decreased neonatal survival occurred at slightly lower levels.

Sulfoxaflor and its major metabolites produced liver weight and enzyme changes, and tumors in subchronic, chronic and short-term studies. Hepatotoxicity occurred at lower doses in long-term studies compared to short-term studies.

Reproductive effects included an increase in Leydig cell tumors which were not treatment related due to the lack of dose response, the lack of statistical significance for the combined tumors, and the high background rates for this tumor type in F344 rats. The primary effects on male reproductive organs are secondary to the loss of normal testicular function due to the size of the Leydig Cell adenomas. The secondary effects to the male reproductive organs are also not treatment related. It appears that rats are uniquely sensitive to these developmental effects and are unlikely to be relevant to humans.

Clinical indications of neurotoxicity were observed at the highest dose tested in the acute neurotoxicity study in rats. Decreased motor activity was also observed in the mid- and high-dose groups. Since the neurotoxicity was observed only at a very high dose and many of the effects are

not consistent with the perturbation of the nicotinic receptor system, it is unlikely that these effects are due to activation of the nAChR.

Tumors have been observed in rat and mouse studies. In rats, there were significant increases in hepatocellular adenomas in the high-dose males. In mice, there were significant increases in hepatocellular adenomas and carcinomas in high dose males. In female mice, there was an increase in carcinomas at the high dose. Liver tumors in mice were treatment-related. Leydig cell tumors were also observed in the high-dose group of male rats, but were not related to treatment. There was also a significant increase in preputial gland tumors in male rats in the high-dose group. Given that the liver tumors are produced by a non-linear mechanism, the Leydig cell tumors were not treatment-related, and the preputial gland tumors only occurred at the high dose in one sex of one species, the evidence of carcinogenicity was weak.

Ecological Toxicity

Sulfoxaflor (N-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-lambda 4-sulfanylidene]) is a new variety of insecticide as a member of the sulfoxamine subclass of neonicotinoid insecticides. It is considered an agonist of the nicotinic acetylcholine receptor and exhibits excitatory responses including tremors, followed by paralysis and mortality in target insects. Sulfoxaflor consists of two diastereomers in a ratio of approximately 50:50 with each diastereomer consisting of two enantiomers. Sulfoxaflor is systemically distributed in plants when applied. The chemical acts through both contact action and ingestion and provides both rapid knockdown (symptoms are typically observed within 1-2 hours of application) and residual control (generally provides from 7 to 21 days of residual control). Incident reports submitted to EPA since approximately 1994 have been tracked via the Incident Data System. Over the 2012 growing season, a Section 18 emergency use was granted for application of sulfoxaflor to cotton in four states (MS, LA, AR, TN). No incident reports have been received in association with the use of sulfoxaflor in this situation.

Sulfoxaflor is classified as practically non-toxic on an acute exposure basis, with 96-h LC_{50} values of >400 mg a.i./L for all three freshwater fish species tested (bluegill, rainbow trout, and common carp). Mortality was 5% or less at the highest test treatments in each of these studies. Treatment-related sublethal effects included discoloration at the highest treatment concentration (100% of fish at 400 mg a.i./L for bluegill) and fish swimming on the bottom (1 fish at 400 mg a.i./L for rainbow trout). No other treatment-related sublethal effects were reported. For an estuarine/marine sheepshead minnow, sulfoxaflor was also practically non-toxic with an LC_{50} of 288 mg a.i./L. Sublethal effects included loss of equilibrium or lying on the bottom of aquaria at 200 and 400 mg a.i./L. The primary degradate of sulfoxaflor is also classified as practically non-toxic to rainbow trout on an acute exposure basis (96-h LC_{50} >500 mg a.i./L).

Adverse effects from chronic exposure to sulfoxaflor were examined with two fish species (fathead minnow and sheepshead minnow) during early life stage toxicity tests. For fathead minnow, the 30-d NOAEC is 5 mg a.i./L based on a 30% reduction in mean fish weight relative to controls at the next highest concentration (LOAEC=10 mg a.i./L). No statistically significant and/or treatment-related effects were reported for hatching success, fry survival and length. For sheepshead minnow, the 30-d NOAEC is 1.3 mg a.i./L based on a statistically significant reduction

in mean length (3% relative to controls) at 2.5 mg a.i./L. No statistically significant and/or treatment-related effects were reported for hatching success, fry survival and mean weight.

The acute toxicity of sulfoxaflor was evaluated for one freshwater invertebrate species, the water flea and two saltwater species (mysid shrimp and Eastern oyster). For the water flea, the 48-h EC₅₀ is >400 mg a.i./L, the highest concentration tested. For Eastern oyster, new shell growth was significantly reduced at 120 mg a.i./L (75% reduction relative to control). The 96-h EC₅₀ for shell growth is 93 mg a.i./L. No mortality occurred at any test concentration. Mysid shrimp are the most acutely sensitive invertebrate species tested with sulfoxaflor based on water column only exposures, with a 96-h LC₅₀ of 0.67 mg a.i./L. The primary degradate of sulfoxaflor is also classified as practically non-toxic to the water flea (EC₅₀ >240 mg a.i./L).

The chronic effects of sulfoxaflor to the water flea were determined in a semi-static system over a period of 21 days to nominal concentrations of 6.25, 12.5, 25, 50 and 100 mg a.i./L. Adult mortality, reproduction rate (number of young), length of the surviving adults, and days to first brood were used to determine the toxicity endpoints. No treatment-related effects on adult mortality or adult length were observed. The reproduction rate and days to first brood were significantly ($p < 0.05$) different in the 100 mg a.i./L test group (40% reduction in mean number of offspring; 35% increase in time to first brood). No significant effects were observed on survival, growth or reproduction at the lower test concentrations. The 21-day NOAEC and LOAEC were determined to be 50 and 100 mg a.i./L, respectively.

The chronic effects of sulfoxaflor to mysid shrimp were determined in a flow-through system over a period of 28 days to nominal concentrations of 0.063, 0.13, 0.25, 0.50 and 1.0 mg a.i./L. Mortality of parent (F₀) and first generation (F₁), reproduction rate of F₀ (number of young), length of the surviving F₀ and F₁, and days to first brood by F₀ were used to determine the toxicity endpoints. Complete F₀ mortality (100%) was observed at the highest test concentration of 1.0 mg a.i./L within 7 days; no treatment-related effects on F₀/F₁ mortality, F₀ reproduction rate, or F₀/F₁ length were observed at the lower test concentrations. The 28-day NOAEC and LOAEC were determined to be 0.11 mg and 0.25 mg a.i./L, respectively.

Sulfoxaflor exhibited relatively low toxicity to aquatic non-vascular plants. The most sensitive aquatic nonvascular plant is the freshwater diatom with a 96-h EC₅₀ of 81.2 mg a.i./L. Similarly, sulfoxaflor was not toxic to the freshwater vascular aquatic plant, *Lemna gibba*, up to the limit amount, as indicated by a 7-d EC₅₀ for frond count, dry weight and growth rate of >100 mg a.i./L with no significant adverse effects on these endpoints observed at any treatment concentration.

Based on an acute oral LD₅₀ of 676 mg a.i./kg bw for bobwhite quail, sulfoxaflor is considered slightly toxic to birds on an acute oral exposure basis. On a subacute, dietary exposure basis, sulfoxaflor is classified as practically nontoxic to birds, with 5-d LC₅₀ values of >5620 mg/kg-diet for mallard ducks and bobwhite quail. The NOAEL from these studies is 5620 mg/kg-diet as no treatment related mortality or sublethal effects were observed at any treatment. Similarly, the primary degradate is classified as practically nontoxic to birds on an acute oral exposure basis with a LD₅₀ of >2250 mg a.i./kg bw. In two chronic, avian reproductive toxicity studies, the 20-week NOAELs ranged from 200 mg/kg-diet (mallard, highest concentration tested) to 1000 mg/kg-diet

(bobwhite quail, highest concentration tested). No treatment-related adverse effects were observed at any test treatment in these studies.

For bees, sulfoxaflor is classified as very highly toxic with acute oral and contact LD₅₀ values of 0.05 and 0.13 µg a.i./bee, respectively, for adult honey bees. For larvae, a 7-d oral LD₅₀ of >0.2 µg a.i./bee was determined (45% mortality occurred at the highest treatment of 0.2 µg a.i./bee). The primary metabolite of sulfoxaflor is practically non-toxic to the honey bee. This lack of toxicity is consistent with the cyano-substituted neonicotinoids where similar cleavage of the cyanide group appears to eliminate their insecticidal activity. The acute oral toxicity of sulfoxaflor to adult bumble bees (*Bombus terrestris*) is similar to the honey bee; whereas its acute contact toxicity is about 20X less toxic for the bumble bee. Sulfoxaflor did not demonstrate substantial residual toxicity to honey bees exposed via treated and aged alfalfa (i.e., mortality was <15% at maximum application rates).

At the application rates used (3-67% of US maximum), the direct effects of sulfoxaflor on adult forager bee mortality, flight activity and the occurrence of behavioral abnormalities is relatively short-lived, lasting 3 days or less. Direct effects are considered those that result directly from interception of spray droplets or dermal contact with foliar residues. The direct effect of sulfoxaflor on these measures at the maximum application rate in the US is presently not known. When compared to control hives, the effect of sulfoxaflor on honey bee colony strength when applied at 3-32% of the US maximum proposed rate was not apparent in most cases. When compared to hives prior to pesticide application, sulfoxaflor applied to cotton foliage up to the maximum rate proposed in the US resulted in no discernible decline in mean colony strength by 17 days after the first application. Longer-term results were not available from this study nor were concurrent controls included. For managed bees, the primary exposure routes of concern include direct contact with spray droplets, dermal contact with foliar residues, and ingestion through consumption of contaminated pollen, nectar and associated processed food provisions. Exposure of hive bees via contaminated wax is also possible. Exposure of bees through contaminated drinking water is not expected to be nearly as important as exposure through direct contact or pollen and nectar.

In summary, sulfoxaflor is slightly toxic to practically non-toxic to fish and freshwater aquatic invertebrates on an acute exposure basis. It is also practically non-toxic to aquatic plants (vascular and non-vascular). Sulfoxaflor is highly toxic to saltwater invertebrates on an acute exposure basis. The high toxicity of sulfoxaflor to mysid shrimp and benthic aquatic insects relative to the water flea is consistent with the toxicity profile of other insecticides with similar MOAs. For birds and mammals, sulfoxaflor is classified as moderately toxic to practically non-toxic on an acute exposure basis. The threshold for chronic toxicity (NOAEL) to birds is 200 ppm and that for mammals is 100 ppm in the diet. Sulfoxaflor did not exhibit deleterious effects to terrestrial plants at or above its proposed maximum application rates.

For bees, sulfoxaflor is classified as very highly toxic. However, if this insecticide is strictly used as directed on the Section 18 supplemental label, no significant adverse effects are expected to Louisiana wildlife. Of course, standard precautions to avoid drift and runoff to waterways of the state are warranted. As stated on the Section 3 label, risk to managed bees and native pollinators

from contact with pesticide spray or residues can be minimized when applications are made before 7 am or after 7 pm or when the temperature is below 55°F at the site of application.

Environmental Fate

Sulfoxaflor is a systemic insecticide which displays translaminar movement when applied to foliage. Movement of sulfoxaflor within the plant follows the direction of water transport within the plant (i.e., xylem mobile) as indicated by phosphor translocation studies in several plants. Sulfoxaflor is characterized by a water solubility ranging from 550 to 1,380 ppm. Sulfoxaflor has a low potential for volatilization from dry and wet surfaces (vapor pressure= 1.9×10^{-8} torr and Henry's Law constant= 1.2×10^{-11} atm m³ mole⁻¹, respectively at 25 °C). Partitioning coefficient of sulfoxaflor from octanol to water (K_{ow} @ 20 C & pH 7= 6; Log K_{ow} = 0.802) suggests low potential for bioaccumulation. No fish bioconcentration study was provided due to the low K_{ow} , but sulfoxaflor is not expected to bioaccumulate in aquatic systems. Furthermore, sulfoxaflor is not expected to partition into the sediment due to low K_{oc} (7-74 mL/g).

Registrants tests indicate that hydrolysis, and both aqueous and soil photolysis are not expected to be important in sulfoxaflor dissipation in the natural environment. In a hydrolysis study, the parent was shown to be stable in acidic/neutral/alkaline sterilized aqueous buffered solutions (pH values of 5, 7 and 9). In addition, parent chemical as well as its major degradate, were shown to degrade relatively slowly by aqueous photolysis in sterile and natural pond water ($t^{1/2}$ = 261 to >1,000 days). Furthermore, sulfoxaflor was stable to photolysis on soil surfaces. Sulfoxaflor is expected to biodegrade rapidly in aerobic soil (half-lives <1 day). Under aerobic aquatic conditions, biodegradation proceeded at a more moderate rate with half-lives ranging from 37 to 88 days. Under anaerobic soil conditions, the parent compound was metabolized with half-lives of 113 to 120 days while under anaerobic aquatic conditions the chemical was more persistent with half-lives of 103 to 382 days. In contrast to its short-lived parent, the major degradate is expected to be more persistent than its parent in aerobic/anaerobic aquatic systems and some aerobic soils. In other soils, less persistence is expected due to mineralization to CO₂ or the formation of other minor degradates.

In field studies, sulfoxaflor has shown similar vulnerability to aerobic bio-degradation in nine out of ten terrestrial field dissipation studies on bare-ground/cropped plots (half-lives were <2 days in nine cropped/bare soils in CA, FL, ND, ON and TX and was 8 days in one bare ground soil in TX). The chemical can be characterized by very high to high mobility (K_{foc} ranged from 11-72 mL g⁻¹). Rapid soil degradation is expected to limit chemical amounts that may potentially leach and contaminate ground water. Contamination of groundwater by sulfoxaflor will only be expected when excessive rain occurs within a short period (few days) of multiple applications in vulnerable sandy soils. Contamination of surface water by sulfoxaflor is expected to be mainly related to drift and very little due to run-off. This is because drifted sulfoxaflor that reaches aquatic systems is expected to persist while that reaching the soil system is expected to degrade quickly with slight chance for it to run-off.

When sulfoxaflor is applied foliarly on growing crops it is intercepted by the crop canopy. Data presented above appear to indicate that sulfoxaflor enters the plant and is incorporated in the plant foliage with only limited degradation. It appears that this is the main source of the insecticide

sulfoxaflor that would kill sap sucking insects. This is because washed-off sulfoxaflor, that reaches the soil system, is expected to degrade.

In summary, sulfoxaflor has a low potential for volatilization from dry and wet surfaces. This chemical is characterized by a relatively higher water solubility. Partitioning coefficient of sulfoxaflor from octanol to water suggests low potential for bioaccumulation in aquatic organisms such as fish. Sulfoxaflor is resistant to hydrolysis and photolysis but transforms quickly in soils. In contrast, sulfoxaflor reaching aquatic systems by drift is expected to degrade rather slowly. Partitioning of sulfoxaflor to air is not expected to be important due to the low vapor pressure and Henry's Law constant for sulfoxaflor. Exposure in surface water results from the drifted parent compound, and only minor amounts are expected to run-off only when rainfall and/or irrigation immediately follow application. The use of this insecticide is not expected to adversely impact Louisiana ecosystems when used according to the Section 18 label. Of course, caution is needed to prevent exposure to water systems because of toxicity issues to aquatic invertebrates. As stated on the Section 3 label, this product should never be applied directly to water, to areas where surface water is present or to intertidal areas below the mean water mark. Also, the label includes the statement "Do not contaminate water when disposing of equipment rinsate."

Endangered and Threatened Species in Kentucky

No impacts are expected on endangered and threatened species by this very limited use of this insecticide as delineated in the Section 18 application. Sulfoxaflor demonstrates a very favorable ecotoxicity and fate profile as stated above and should not directly impact any protected mammal, fish, avian, or plant species. This product does adversely affect insects and aquatic invertebrates, especially bees, but the limited exposure to these species should not negatively affect endangered and threatened species in Tennessee when all applications label precautions are followed and preformed.

The above content in Section 166.20(a)(7): Discussion of Risk Information was, for the most part, prepared by Michael Hare, Ph.D. (Human Health Effects), David Villarreal, Ph.D. (Ecological Effects), and David Villarreal, Ph.D. (Environmental Fate), all with the Texas Department of Agriculture. Some parts of the above content in this section were prepared by MDAC-BPI

SECTION 166.20(a)(8): COORDINATION WITH OTHER AFFECTED STATE OR FEDERAL AGENCIES

The Kentucky Department of Fish and Wildlife Resources will receive a copy of this request.

SECTION 166.20(a)(9): ACKNOWLEDGEMENT BY THE REGISTRANT

Dow AgroSciences has been notified of this agency's intent regarding this application and has provided a letter of support (appended). They have also provided a copy of a label with the use directions for this use (although this use is dependent upon the approval of this section-18 by EPA).

SECTION 166.20(a)(10): DESCRIPTION OF PROPOSED ENFORCEMENT PROGRAM

The Kentucky Department of Agriculture (KDA) has adequate authorities for enforcing provisions of Section 18 emergency exemptions. KDA will require Dow AgroSciences to prepare Section 18 labeling that complies with KDA and EPA requirements for this emergency use, if approves, to ensure that product distributed for the exemption is properly labeled.

SECTION 166.20(a)(11): REPEAT USES

None to date

SECTION 166.20(b)(1): NAME OF THE PEST

Melanaphis sacchari, sugarcane aphid

SECTION 166.20(b)(2): DISCUSSION OF EVENTS OR CIRCUMSTANCES WHICH BROUGHT ABOUT THE EMERGENCY SITUATION

Since SCA was first reported as a pest in grain sorghum during 2013, it had spread rapidly across the South. The SCA has not yet been collected in KY. However, it has been collected in Tennessee counties that border Kentucky counties and was problematic in Missouri counties near Kentucky. Additional comments under SECTION 166.20(b)(4) and Attachments 6 and 7 are publications from Texas and Arkansas, respectively, which detail the history, biology, damage, and control options for SCA. Because we expect this aphid to persist at treatment levels in sorghum approaching harvest, there is a great need for efficacious insecticides that have relatively short pre-harvest interval restrictions. With the possible exception of Sivanto (previously discussed), Transform WG will provide the only reliable insecticide for the control of this pest.

SECTION 166.20(b)(3): DISCUSSION OF ANTICIPATED RISKS TO ENDANGERED OR THREATENED SPECIES, BENEFICIAL ORGANISMS, OR THE ENVIRONMENT REMEDIED BY THE PROPOSED USE

As previously stated, it is not anticipated that there should be any anticipated risk to endangered or threatened species, beneficial organisms, or the environment if all applications are made in accordance to the Section 18 use directions.

SECTION 166.20(b)(4): DISCUSSION OF SIGNIFICANT ECONOMIC LOSS

Losses have not yet occurred in Kentucky. Nevertheless, given the close proximity of infestations in Tennessee and Missouri counties to the south and west of Kentucky. We feel that Kentucky producers are facing an urgent situation for the 2015 growing season for a Non-routine pest for which we would like to be prepared. We are fortunate to be able to learn how to deal with this pest from our more southern neighbors. Tennessee was spared substantial economic losses in 2014 owing to the late arrival of this pest and that the Section 18 that was granted for Transform. Nevertheless, during 2014, the majority of late-planted grain sorghum fields were sprayed at least once in the counties of Tipton, Shelby, Haywood, Chester, Fayette, Chester, McNairy, Hardin, Hardeman, and Lauderdale. It is unclear how much yield loss was suffered in these fields, but some fields were already heavily infested at the time of application, and some unsprayed fields of sweet sorghum were subsequently devastated. Several growers have indicated that honeydew interfered with harvesting operations. It is clear that some fields of grain sorghum would have suffered catastrophic losses had Transform WG not been applied.

The 2014 and 2015 requests from Louisiana (see attached for 2014), Mississippi, and Arkansas indicated that 5-100% yield losses have occurred in infested fields. In 2014, Extension Specialists in both Arkansas and Mississippi have reported catastrophic yield losses approaching 100% in some fields in these states. Economic losses are expected occur in Tennessee, at least in late planted sorghum fields, if infestations continue to expand. Because of market-driven factors, growers have indicated that grain sorghum acres will increase by 2-3 fold in 2015. Thus, Tennessee growers will be at potentially greater risk to economic injury from SCA in 2015.